PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING DOCUMENT TRANSMITTED

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as designated Office

Date of mailing (day/month/year)	
19 January 2001 (19.01.01)	
International application No.	**International filing date** (day/month/year)
PCT/IB99/01735	26 October 1999 (26.10.99)
Applicant	
RANBAXY LABORATORIES LIMITED et al	

The International Bureau transmits herewith the following documents and number thereof:

_____ cop(ies) of priority document(s) (Rule 17.2(a))

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer R. Chrem
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

DESHMUKH, Jayadeep, R.
Ranbaxy Pharmaceuticals, Inc.
Suite 2100
600 College Road East
Princeton, NJ 08540
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 19 January 2001 (19.01.01)	
Applicant's or agent's file reference RLL-165 WO	**IMPORTANT NOTIFICATION**
International application No. PCT/IB99/01735	International filing date (day/month/year) 26 October 1999 (26.10.99)
International publication date (day/month/year) 28 September 2000 (28.09.00)	Priority date (day/month/year) 19 March 1999 (19.03.99)
Applicant RANBAXY LABORATORIES LIMITED et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
19 Marc 1999 (19.03.99)	454/DEL/99	IN	22 Dece 2000 (22.12.00) *

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

R. Chrem

Telephone No. (41-22) 338.83.38

PA. _NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 February 2001 (15.02.01)	
International application No. PCT/IB99/01735	**Applicant's or agent's file reference** RLL-165 WO
International filing date (day/month/year) 26 October 1999 (26.10.99)	**Priority date** (day/month/year) 19 March 1999 (19.03.99)
Applicant MUKHERJI, Gour et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

25 September 2000 (25.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JAYADEEP R. DESHMUKH
RANBAXY PHARMACEUTICALS, INC.
600 COLLEGE ROAD EAST, SUITE 2100
PRINCETON, NJ 08540

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference RLL-165 WO	Date of Mailing *(day/month/year)* 16 MAY 2000 **FOR FURTHER ACTION** **See paragraphs 1 and 4 below**
International application No. PCT/IB99/01735	International filing date *(day/month/year)* 26 OCTOBER 1999
Applicant RANBAXY LABORATORIES LIMITED	

1. [X] The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM BENSTON Telephone No. (703) 308-1235

Form PCT/ISA/220 (July 1998)★

(See notes on accompanying sheet)

MAY 19 2000

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-165 WO	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IB99/01735	International filing date *(day/month/year)* 26 OCTOBER 1999	(Earliest) Priority Date *(day/month/year)* 19 MARCH 1999
Applicant RANBAXY LABORATORIES LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readable form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

MAY 19 2000

09/936934

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 September 2000 (28.09.2000)

PCT

(10) International Publication Number
WO 00/056266 A3

(51) International Patent Classification[7]: A61K 9/14

(21) International Application Number: PCT/IB99/01735

(22) International Filing Date: 26 October 1999 (26.10.1999)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
454/DEL/99 19 March 1999 (19.03.1999) IN

(71) Applicant *(for all designated States except US)*: **RANBAXY LABORATORIES LIMITED** [IN/IN]; 19, Nehru Place, New Delhi 110 019 (IN).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MUKHERJI, Gour** [IN/IN]; E-12/31, Phase - 1, DLF Qutab Enclave, Gurgaon - 122 002, Haryana (IN). **KUMAR, Manoj** [IN/IN]; House No. 157, Sector - 16A, Faridabad 121 001, Haryana (IN). **SEN, Himadri** [IN/IN]; S-1/19, Phase - III, DLF Qutab Enclave, Gurgaon 122 002, Haryana (IN).

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
4 July 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 00/056266 A3

(54) Title: TASTE MASKING COATING COMPOSITIONS

(57) Abstract: A coating composition is described for the film coating of pharmaceutical cores containing the drug, said composition comprising a suitable film forming material in combination with a high viscosity swellable polymer.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB99/01735

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 9/14
US CL :424/489

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/489

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,958,459 A (CHASIN et al.) 28 September 1999, col. 4, lines 9-16 and 40-44; col. 5, lines 14-28 and 45-52; col. 6, lines 4-31 and 34-55; col. 7, lines 14-22; col. 8, lines 1-9 and 40-56; col. 10, lines 34-56; and col. 13, lin 58.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 MAY 2000	16 MAY 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Dorothea Lawrence for WILLIAM BENSTON Telephone No. (703) 308-1235

Form PCT/ISA/210 (second sheet) (July 1998)★

MAY 19 2000

09/936934

14

PATENT COOPERATION TREATY

PCT

REC'D 05 NOV 2001
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-165 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB99/01735	International filing date *(day/month/year)* 26 October 1999 (26.10.1999)	Priority date *(day/month/year)* 19 March 1999 (19.03.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/14 and US Cl.: 424/489		
Applicant RANBAXY LABORATORIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 25 September 2000 (25.09.2000)	Date of completion of this report 02 October 2001 (02.10.2001)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Amy E. Pulliam Telephone No. (703) 308-1234

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IB99/01735

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-20 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 21-23 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/??99/?????
JD99/01435

ID

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	3,5-13,15-17	YES
	Claims	1,2,4,14,18	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-18	NO
Industrial Applicability (IA)	Claims	1-18	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 2, 4, 14, and 18 lack novelty under PCT Article 33(2) as being anticipated by Us Patent 4,606,771 to MUKOHYAMA *et al.*. MUKOHYAMA *et al.* teach an aqueous enteric coating composition. More specifically, they teach that various additives may be employed in their claimed coating composition, including a film forming assistant such as hydroxypropyl cellulose, a natural hum such as carrageenan or guar gum, and a plasticizer such as triethyl citrate or a di, tri, or monoglyceride (column 4, line 54 - column 5, line 4). MUKOHYAMA *et al.* further teach that their coating composition may be used with tablets, capsules, and granules (column 5, lines 50-55).

Claims 1-6, and 14-18lack an inventive step under PCT Article 33(3) as being obvious over MUKOHYAMA *et al.*, as discussed above. MUKOHYAMA *et al.* do not teach the specific weight percent as claimed by applicant. However, it is the position of the examiner that the specific percentages are limitation which would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presence of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations. Furthermore, as MUKOHYAMA *et al.* teach a successful coating composition, it appears that there is not criticality in the specific weight percents. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-18 lack an inventive step under PCT Article 33(3) as being obvious over MUKOHYAMA *et al.*, as discussed above in view of US Patent 5,622,721 to DANDEREAU *et al.* MUKOHYAMA *et al.* are discussed above as teachings an enteric coating composition. MUKOHYAMA *et al.* do not disclose all the possible additives for inclusion in the coating composition, as claimed by applicant. DANSEREAU *et al.* disclose a pharmaceutical formulation, more specifically one that is coated with an enteric coating, such as Eudragit (column 10, line 3). However, the disclosure of DANSEREAU *et al.* is relied upon for the teachings found at column 10l, lines 42-50, which lists excipieints which are well known for use in pharmaceutical coating compositions. These include talc, magnesium stearate, and plasticizers such as polyethylene glycol and triethyl citrate. It is the position of the examiner that one of ordinary skill in the pharmaceutical art would have been motivated to include well known excipients, such as lubricants and plasticizers in the coating composition disclose by MUKOHYAMA *et al.*. The expected result would be a successful coating composition. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-18 meet the criteria set out in PCT Article 33(4) because a coating composition would have industrial applicability in the pharmaceutical industry.

----------NEW CITATIONS----------

US 4,606,771 A (MUKOHYAMA *et al.*) 19 August 1986 (19.08.1986), see column 4, lines 54-69, column 5, lines 1-5, column 5, lines 50-55.

US 5,622,721 A (DANSEREAU *et al.*) 22 April 1997 (22.04.1997), see column 6, lines 52-65, column 7, lines 44-50, column , lines 65-69, column 10, lines 42-50.

09/936934

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61K

A2

(11) International Publication Number: WO 00/56266

(43) International Publication Date: 28 September 2000 (28.09.00)

(21) International Application Number: PCT/IB99/01735

(22) International Filing Date: 26 October 1999 (26.10.99)

(30) Priority Data:
454/DEL/99 19 March 1999 (19.03.99) IN

(71) Applicant *(for all designated States except US)*: RANBAXY LABORATORIES LIMITED [IN/IN]; 19, Nehru Place, New Delhi 110 019 (IN).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: MUKHERJI, Gour [IN/IN]; E–12/31, Phase – 1, DLF Qutab Enclave, Gurgaon – 122 002, Haryana (IN). KUMAR, Manoj [IN/IN]; House No. 157, Sector – 16A, Faridabad 121 001, Haryana (IN). SEN, Himadri [IN/IN]; S–1/19, Phase – III, DLF Qutab Enclave, Gurgaon 122 002, Haryana (IN).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: TASTE MASKING COATING COMPOSITIONS

(57) Abstract

A coating composition is described for the film coating of pharmaceutical cores containing the drug, said composition comprising a suitable film forming material in combination with a high viscosity swellable polymer.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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INTERNATION... SEARCH REPORT

In...national application No.
PCT/IB99/01735

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 9/14
US CL :424/489

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/489

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,958,459 A (CHASIN et al.) 28 September 1999, col. 4, lines 9-16 and 40-44; col. 5, lines 14-28 and 45-52; col. 6, lines 4-31 and 34-55; col. 7, lines 14-22; col. 8, lines 1-9 and 40-56; col. 10, lines 34-56; and col. 13, lin 58.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search 04 MAY 2000	Date of mailing of the international search report 16 MAY 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM BENSTON Telephone No. (703) 308-1235

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TASTE MASKING COATING COMPOSITIONS

FIELD OF THE INVENTION

The present invention relates to a coating composition effective for taste masking of bitter and unpalatable drugs.

BACKGROUND OF THE INVENTION

Most prescription and non-prescription drugs are administered orally as tablets or capsules. However, patients at the extremes of age, such as children and the elderly, often experience difficulty in swallowing such solid dosage forms. For such patients drugs can be provided either as chewable or dispersible tablets or, as liquid dosage forms such as solutions, emulsions and suspensions. These dosage forms permit perceptible exposure of the active drug to the taste buds. Some drugs are extremely bitter and therefore unpalatable when given in these dosage forms. As a consequence, measures need to be taken to mask the taste of these drugs in order to enhance patient compliance.

Several techniques to make liquid dosage forms palatable, are reported in the literature. These include the use of relatively insoluble salts of the parent drug resulting in lower exposure of the drug in perceptible form in the mouth. Syrups with or without flavouring, are often sufficient to mask the taste of drugs. However, some drugs have such a pronounced bitterness that conventional approaches such as the use of sweetners, amino acids, flavors and adsorbents are unsuccessful. This is particularly problematic if the drug in question is extensively used in treating children or the elderly. There is, therefore, a need to develop approaches that would be effective in masking the taste of bitter drugs.

US 4,808,411 describes a taste masked pharmaceutical composition comprising erythromycin or its derivatives and a carbomer. The drug-polymer complex is believed to be held together by ionic attraction between the amine group of erythromycin compound and carbonyl group of the carbomer, and by the gel properties of the insoluble carbomer. This provides for a minimal dissolution of the erythromycin compound in a non-ionic aqueous medium, so that the drug is released from the complex slowly enough to avoid a significant perception of bitterness in the mouth. In the gastro-intestinal tract, the ionic environment causes liberation of the erythromycin compound. Thus, by controlling the availability of the drug in the free form, taste masking of the drug is achieved. This method, however, will be useful for masking the taste of only those drugs which can form reversible complexes and will, therefore, be limited in its utility.

US 4,865,851 describes a taste masked formulation of cefuroxime axetil where the drug particles are provided with integral coatings of a lipid or mixtures of lipids which are insoluble in water and which serve to mask the bitter taste of cefuroxime axetil upon oral administration. This coating however, results in a significant reduction in the dissolution and consequently the bioavailability of cefuroxime axetil suspension is significantly low as compared to tablet dosage form.

US 5,695,784 describes a method for taste masking of bitter drugs where the coating composition comprises a cationic copolymer of dimethylaminoethyl methacrylate and neutral methacrylate acid esters, neutral methyl esters and/or ethyl ester compounds of polymethacrylic acid, quaternary ammonium compounds of

polymethacrylic acid or ethylcellulose and triethylcitrate and optionally hydroxypropyl methylcellulose. This coating composition requires the application of large quantities of polymers for effective taste masking.

SUMMARY OF THE INVENTION

The present invention describes coating compositions and processes for the preparation of a pharmaceutical coating composition, effective in masking the taste of medicinal compounds, to be applied over the core constituted of medicinal compound. The core may comprise primary drug particles, granules, crystals, pellets or even unit dosage forms like tablets. The coat comprises a film forming polymer and a high viscosity swellable polymer, optionally also including other suitable ingredients for coating including lubricants, plasticizers and channeling agents.

The combination of film forming polymer with swellable polymer imparts in the film a barrier property for the control of initial drug release suitable for taste-masking, without compromising on drug release over the stipulated duration of a conventional, immediate release formulation. For very bitter drugs polymer applications may be as high as 80% on fine cores using conventional coating polymers. The present composition is capable of achieving the same degree of taste masking in as little as 10 to 15% of polymer application, equivalent to 20 - 30% of total solids applied. This, therefore, results in uniformity of coating thickness, process reproducibility, faster rate of dissolution and uncompromised bioavailability. It also makes the process cost effective and less time consuming.

A variety of polymeric materials can be employed for film forming. Non-limiting examples of such film forming polymers may belong to the class of acrylic polymers, cellulosic polymers or vinyl polymers. The acrylic polymers used will be those available under the trade name Eudragit® from Rohm Pharma. More preferably the acrylic polymers may be methacrylic acid co-polymers sold under the trade name Eudragit L® and Eudragit S®, and polyethylacrylate-methylmethacrylate sold under the trade name, Eudragit NE®.

Cellulosic film-forming agents which are useful, include, alkylcelluloses, such as, methyl or ethyl cellulose and, hydroxyalkylcelluloses (eg., hydroxypropylcellulose or hyroxypropylmethyl-celluloses). The alkyl cellulosic film forming polymers include those sold under the trade names Methocel E™ and Surelease by Dow Chemicals, and Aquacoat® of FMC. Examples of vinyl film forming polymers include polyvinyl acetate or polyvinyl acetate pthalate. The dry weight of the film forming polymer may be applied to a maximum of 30% of the weight of the core for taste masking.

The swellable polymers which may be used in combination with the film forming polymers include carbopol, high viscosity gums, carrageenan, high viscosity vinyl polymers or high viscosity cellulosic polymers such as Methocel™ K series polymers (Trademark Dow Chemicals). Swellable polymers may be present from 0.1 - 20% of the dry weight of film forming polymer.

The coating composition may optionally include pharmaceutically acceptable excipients, which are conventionally used as a channeling agent such as starch, lactose or (PEG) poly ethylene glycol. The channeling agent may be present upto

100%, preferably 60%, or more preferably, upto 30% of the dry weight of the film forming polymer.

The coating composition also contains lubricants which function as anti-sticking agents (e.g. talc, colloidal silica and magnesium stearate) and pharmaceutically acceptable plasticisers (e.g. triethyl citrate, polyethylene glycol, glyceryl monostearate, glyceryl triacetate, acetyl triethylcitrate, triethylcitrate, dibutyl phthalate and dibutyl sebacate). The lubricant quantity may be upto 200% of the dry weight of film-forming polymer, and more preferably, upto 100% of the dry weight of the film-forming polymer. The plasticiser quantity may be upto 40% the dry weight of the film forming polymer. The coated formulations may optionally be cured at elevated temperatures.

A total polymer content in the coating of upto 30% by weight of pharmaceutical cores or, more preferably, 10% by weight of pharmaceutical cores is sufficient to mask the taste of bitter tasting, highly water soluble drugs.

The taste masked coated particles obtained by the composition of the present invention, can be mixed with food or beverages, can be used to prepare liquid suspensions for oral administration, or can be formulated into conventional whole, chewable, or dispersible tablets for oral administration. In forming tablets or liquid suspensions, pharmaceutically acceptable ingredients well known in conventional arts can be employed. For use in suspensions, a mean average particle size of less than 50 mesh (297 microns) is preferred. The drug may optionally be first formulated as pellets, tablets or capsules, which may then be coated for taste-masking.

The examples given herein further illustrate the invention and are not intended to limit the scope of the invention:

DETAILED DESCRIPTION OF THE INVENTION

EXAMPLE 1

Table 1.1 shows a coating composition which has been used for taste masking of a number of drug cores :

Table 1.1

Ingredient	Amount used (g)	Dry wt. (g)
Eudragit L30D	333.33	100.0
Carbomer (Aqueous Carbopol® 971P Dispersion 1% w/w)	200.0	2.0
Talc USP (Aqueous Talc Dispersion 30% w/w)	40.80	102.0
Polyethylene glycol USNF (PEG 1500)	15.3	15.3
Purified Water USP upto..	1000.00	-

To prepare the coating solution, an aqueous talc dispersion (30% w/w), was added to a 1% w/w carbopol dispersion in water under stirring for 30 minutes.

Carbopol-talc dispersion was finally added into plasticized (with PEG 1500) Eudragit dispersion with stirring for 30-40 minutes.

Procedure for preparation of core particles :

Table 1.2

Ingredient	Amount used (g)
Norfloxacin USP	260.0
Microcrystalline Cellulose USNF (Avicl® PH 102)	88.0
Pregelatinized Starch USNF (Sarch 1500)	10.0
Povidone USP (PVP K-30)	30.0
Colloidal Silicon Dioxide USNF (Aerosil® 200)	2.0
Magnesium Stearate USNF	0.75

Weighed amount of ingredients (except Aerosil 200) were sifted through British Standard Sieve (BSS) #44 and mixed for 10 minutes in a double cone blender, followed by the addition of Aerosil 200 (sifted through BSS #60) and an additional mixing of 2 minutes. The blend was then granulated with water and dried at 60°C in a tray-drier for 24 hours. The granules obtained were sifted to give (BSS)# 44 / #85 fraction.

Resultant granules (150g) were lubricated with 0.5% magnesium stearate and sprayed with the prepared coating solution using Wurster coater (Glatt GPCG-1 from Glatt GmbH, Germany). The total polymer content of the applied coat was 12.0% by weight of the core while the total solids applied was 26% by weight of the core. A total polymer coating of only 12% was sufficient to mask the bitter taste of Norfloxacin while giving optimum dissolution required for immediate release formulations. (Table 1.3).

Table 1.3

Time (Min.)	Percent drug released USP Buffer pH 4.0; 50rpm; 900ml	
	Uncoated	Coated
5	63.80	2.30
10	95.73	19.40
15	106.40	38.30
20	--	54.23
25	--	66.37
30	--	82.17

EXAMPLE 2

In this example, ibuprofen was granulated and coated for taste masking, as discussed below.

Table 2.1

Ingredient	Amount used (g)
Ibuprofen USP	260.0
Microcrystalline Cellulose (Avicel® PH 102)	88.0
Pregelatinized Starch USNF (Starch 1500)	10.0
Povidone USP (PVP K-30)	30.0
Colloidal Silicon Dioxide USNF (Aerosil® 200)	2.0
Magnesium Stearate USNF	0.75

Weighed amounts of Ibuprofen, Avicel 102, Starch 1500 and PVP K-30 were sifted through BSS #44 and mixed for 10 mins. in a double cone blender. Aerosil 200 was sifted through BSS #60 and added to the blend in the double cone blender and mixed for an additional 2 minutes. The blend was granulated with water and dried at 60°C in a tray drier for 4 hours. After sifting through BSS #44 and BSS #85, the #44/85 fraction (150gm) was lubricated with magnesium stearate (0.75g). The dried and lubricated granules (150.0g) were sprayed with the prepared coating solution as described in Example 1(Table 1.1). Only a 6% coating of polymers by weight of the core (total solids applied was 13%) was sufficient to mask the taste of ibuprofen. Coated granules when kept in the mouth for 1-2 minutes, did not give any bitter taste. The dissolution of ibuprofen was not significantly affected by this coat, as shown in the Table 2.2.

Table 2.2

Time (Min.)	Percent drug released Phosphate Buffer pH 7.2; 150rpm; 900ml	
	Uncoated	Coated
5	54.30	46.27
10	85.63	76.03
15	94.06	88.97
20	97.00	93.37
25	97.40	93.00
30	97.90	94.70

EXAMPLE 3

Table 3.1

Ingredient	Amount used (g)
Etodolac BP	200.0
Microcrystalline Cellulose USNF (Avicel® PH 102)	148.0
Pregelatinized Starch USNF (Starch 1500)	10.0
Povidone USP (PVP K-30)	30.0
Colloidal Silicon Dioxide USNF (Aerosil® 200)	2.0
Magnesium Stearate USNF	0.75

Etodolac, Avicel PH 102, Starch 1500 and PVP K-30 were blended in a double cone blender. Aerosil 200, sifted through BSS #60, was added to the blend and mixed for 2 minutes. The blend was granulated with water and dried at 60°C for 4 hours. Dried material was sifted to obtain fraction of BSS #44/85 and lubricated with magnesium stearate (0.75g). The dried and lubricated granules (150.g) were sprayed with the prepared coating solution as described in Example 1 (Table 1.1). The total polymer coating of 12.0% by weight of the core was sufficient to mask the bitter taste of the drug. The total solids applied was 26%. The coated granules gave optimum dissolution as shown in Table 3.2.

Table 3.2

Time (Min.)	Percent drug released Phosphate Buffer pH 7.5; 100rpm; 900ml	
	Uncoated	Coated
5	86.60	29.70
10	91.37	73.10
15	93.43	88.00
20	94.00	92.80
25	--	94.40
30	--	94.90

EXAMPLE 4

Table 4.1

Ingredient	Amount used (g)
Paracetamol USP	260.0
Microcrystalline Cellulose USNF (Avicel® PH 102)	88.0
Pregelatinized Starch USNF (Starch 1500)	10.0
Povidone USP (PVP K-30)	30.0
Colloidal Silicon Dioxide USNF (Aerosil® 200)	2.0
Magnesium Stearate upto	0.75

Paracetamol, Avicel PH 102, Starch 1500 and PVP K-30 were blended in double cone blender. Aerosil 200 was sifted through BSS #60 and blended for 2 minutes. The blend was granulated with water and dried at 60°C for 4-5 hours. 150 g of the dried fraction (BSS #44/85) was lubricated with magnesium stearate (0.75 g). The dried and lubricated granules (150g) were sprayed with the prepared coating solution as described in Example 1 (Table 1.1). The total polymer and solids applied were 8% and 17.5% by weight of the core, respectively which was sufficient to mask the taste of the drug without affecting the dissolution (Table 4.2).

Table 4.2

Time (Min.)	Percent drug released Phosphate Buffer pH 5.8; 50rpm; 900ml	
	Uncoated	Coated
5	76.10	61.90
10	96.30	86.60
15	96.90	92.60
20	97.00	94.10
25	97.40	94.40
30	--	94.90

EXAMPLE 5

Table 5.1

Ingredient	Amount used (g)
Ciprofloxacin Hydrochloride USP (equivalent to 200g Ciprofloxacin USP)	239.0
Hydroxypropyl Cellulose USNF (HPC-L)	11.2
Colloidal silicon dioxide USNF (Aerosil® 200)	0.75

Microcrystalline cellulose USNF, (Celphere®)	100.0
Talc USP (Aqueous Talc Dispersion 30% w/w)	14.0
Purified Water USP upto	670.0

A dispersion was pepared by dissolving HPC-L in water, followed by the addition of ciprofloxacin hydrochloride and talc with vigorous stirring. The suspension was homogenised for 30 minutes, sieved and coated on 100 g microcrystalline cellulose spheres (Celphere® , FMC Corp., USA) having an average particle size of 170μm.

Procedure for layering : Celphere beads (100 g) were introduced into the processing chamber of Wurster coater (Glatt GPCG-1 from Glatt GmbH, Germany) and the prepared drug suspension was sprayed from the bottom at a spray rate of 5 - 9 g/min. After spraying was complete the drug loaded cores were dried.

150 g of the dried cores were lubricated with 0.75 g Aerosil® (sifted through BSS #60 mesh) and sprayed with the prepared coating solution described in Table 5.2, as follows:

Table 5.2

Ingredient	Amount used (g)	Dry wt. (g)
Eudragit L30D	66.67	20.0
Carbomer (Aqueous Carbopol® 971P Dispersion 1% w/w)	40.0	0.40
Polyethylene glycol USNF (PEG 1500)	3.06	3.06
Lactose Monohydrate USNF	2.04	2.04
Talc USP (Aqueous Talc Dispersion 40% w/w)	51.0	20.4
Purified Water USP upto	200.0	--

The total polymer content of the applied coat was 11.90% by weight of the core while the total solids application was 27% by weight of the core. The bitter taste of ciprofloxacin was masked with the applied coat without affecting dissolution, as shown in Table 5.3

Table 5.3

Time (Min.)	Percent drug released 0.1N HCl; 75 rpm; 900ml, USP app-2	
	Uncoated	Coated
5.0	87.0	7.20
10.0	97.8	27.2
15.0	100.7	46.3
20.0	-	62.90
25.0	-	76.0
30.0	-	85.1

EXAMPLE 6

Table 6.1 describes another coating composition containing a film forming polymer (ethyl cellulose) and a swellable polymer (carbopol).

Table 6.1

Ingredient	Amount used (g)	Dry wt. (g)
Ethyl Cellulose Aqueous dispersion USNF (Aquacoat® ECD-30)	100.0	30.0
Carbomer	60.0	0.60

(Aqueous Carbopol® 971P Dispersion 1% w/w)		
Triethyl Citrate USNF	6.0	--
Talc USP (Aqueous Talc Dispersion 30% w/w)	30.0	9.0
Purified Water USP upto	200.0	--

To prepare the coating solution an aqueous talc dispersion (30% w/w) was added to a 1% carbopol dispersion in water under stirring for 30 minutes. The carbopol – talc dispersion was finally added into plasticized (with triethyl citrate) ethyl cellulose dispersion with stirring for 30-40 minutes.

Core containing Paracetamol were prepared using the formula described in Table 6.2.

Table 6.2

Ingredient	Amount used (g)
Paracetamol USP	260.0
Povidone USP (PVP K-30)	28.0
Lactose Monohydrate USNF	18.0
Microcrystalline cellulose USNF (Avicel® PH 101)	90.0
Colloidal Silicon Dioxide USNF (Aerosil® 200)	4.0

Total	400.0

Paracetamol, PVP K-30, Lactose, and Avicel PH 101 were mixed in a double cone blender for 10 minutes. They were then granulated with water, dried in a tray drier at 60°C for 4 hours and sifted to give BSS fraction #30/85. The granules thus obtained were lubricated with Aerosil 200 and sprayed with the prepared coating solution using Wurster Coater (Glatt GPCG–1, GmbH, Germany). The total polymer content of the coat applied was 12% by weight of the core. This coating effectively masked the pungent taste of paracetamol and also gave the desired dissolution profile as shown in Table 6.3

Table 6.3

Time (Min.)	**Percent drug released PH 5.8 Phosphate buffer; 50 rpm; 900ml**	
	Uncoated	**Coated**
5.0	90.1	23.7
10.0	97.7	62.4
15.0	97.9	88.0
20.0	98.1	98.2
25.0	98.3	98.9
30.0	98.4	99.3

EXAMPLE 7

Example 7 deals with the same coating composition as given in Table 6.1, wherein ethyl cellulose has been combined with carbopol in a 100 : 2 proportion. The drug particles which have been coated is constituted of ciprofloxacin base and its composition is described in Table 7.1.

Table 7.1

Ingredient	Amount used (g)
Ciprofloxacin USP	50.0
Lactose Monohydrate USNF	3.5
Povidone USP (PVP K-30)	5.5
Microcrystalline cellulose USNF (Avicel PH101)	17.5
Colloidal Silicon Dioxide USNF (Aerosil 200)	00.75
Total	77.25

Weighed amount of ciprofloxacin, lactose, Avicel PH 101 and PVP K-30 were sifted through BSS #44 and dry mixed in a double cone blender. The blend was granulated with sufficient water to form a cohesive mass. The wet mass was dried in a tray drier and sifted through BSS #30 and retained on BSS #85. The dried material was lubricated with sifted Aerosil (sieved through BSS #60) and then loaded

in Glatt GPCG-1 Wurster for coating with ethyl cellulose-carbopol solution (described in Table 6.1).

A total polymer application of 15% of the weight of the cores (total solids applied were 34.35%) was sufficient to mask the bitter taste of ciprofloxacin without affecting the dissolution significantly.

Table 7.2 shows the dissolution profiles of the coated and uncoated granules using USP apparatus - 2 at 75 rpm in 900 ml of 0.1N hydrochloric acid.

Table 7.2

Time (Min.)	**Percent drug released 0.1N HCl, 75 rpm; 900ml, USP app-II**	
	Uncoated	**Coated**
5.0	83.3	12.8
10.0	97.7	31.7
15.0	97.8	58.7
20.0	98.1	70.8
25.0	-	82.6
30.0	-	95.2

While the present invention has been described in terms of its specific embodiments, certain modifications and equivalents will be apparent to those skilled in the art and are intended to be included within the scope of the present invention.

WE CLAIM :

1 A coating composition, used for the film coating of pharmaceutical cores containing the drug, said composition comprising a suitable film forming material in combination with a high viscosity swellable polymer and optionally other suitable ingredients for coating including lubricants, plasticisers and channeling agents.

2. The composition of claim 1, wherein the film forming material comprises methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, alkyl celluloses or mixtures thereof.

3. The composition of claim 2, wherein the dry weight of the film forming polymer applied is upto a maximum of 30% of the weight of the core.

4. The composition of claim 1, wherein the high viscosity swellable polymer comprises carbopol, carragennan, polyvinyl alcohol, cellulosic polymers or other suitable high viscosity gums.

5. The composition of claim 4, wherein the swellable polymer is present from 0.1 to 20% w/w of the dry weight of film forming polymer.

6. The composition of claim 4, wherein high viscosity swellable polymer is carbopol.

7. The composition of claim 1, wherein channeling agents are included and are selected from the group consisting of lactose, starch, talc and mixtures thereof.

8. The composition of claim 7, wherein the channeling agent is present in an amount up to 100% of the dry weight of polymers.

9. The composition of claim 8, wherein the channeling agent is present in an amount up to 60% of the dry weight of polymers.

10. The composition of claim 9, wherein the channeling agent is present in an amount up to 30% of the dry weight of polymers.

11. The composition of claim 1, wherein the lubricants are present and are selected from the group consisting of talc, glyceryl monostrearate, magnesium stearate, colloidal silica and mixtures thereof.

12. The composition of claim 11, wherein the lubricant is present in an amount up to 200% of the dry weight of the film forming polymer.

13. The composition of claim 12, wherein the lubricant is present in an amount up to 100% of the dry weight of the film forming polymer.

14. The composition of claim 1, wherein the plasticisers are incorporated in the film and are selected from the group consisting of polyethylene glycol, acetylated

monoglycerides, glyceryl monostearate, glyceryl triacetate, acetyl triethylcitrate, triethylcitrate, dibutyl phthalate, dibutyl sebacate and mixtures thereof.

15. The composition of claim 14, wherein the plasticizer is present in an amount upto 40% of the dry weight of film forming polymer.

16. The composition of claim 15, wherein the plasticizer is polyethylene glycol (PEG).

17. The composition of claim 1, which includes 0.5 to 30% of the dry weight of the polymers by weight of the cores.

18. The composition of claim 14, wherein the coated particles are formulated as sprinkles, dry powder, liquitabs, suspension, emulsion, or as whole, chewable, or dispersible tablet, or any other suitable oral dosage forms.